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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,228	10/12/2001	Lothar W. Kleiner	ARC 2427 N1	9517

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ALZA CORPORATION
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EXAMINER

HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,228

Applicant(s)

KLEINER ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,10-13,15,16,34-39,41,47,53,56,59,62-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,10-13,15,16,34-39,41,47,53,56,59 and 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Group I, claims 1,3,10-13,15,16,34-39,41,47,53,56,59,62,63 in the reply filed on 11/17/03 is acknowledged, but since the applicant did not put forth any arguments against the restriction requirement, the restriction requirement herein made is final. The 112 (second para.) rejection has been overcome and is considered withdrawn.

Receipt of the revocation of prior power of attorney, the request to change correspondence address and remarks filed on 11/17/03 has been acknowledged. The terminal disclaimer filed on 11/17/03 over U.S. Patent No. 6,375,978 overcomes the obviousness rejections.

Status of the Claims

Claims 1-64 are pending in this application.

Claim 64 is new and has been added.

Claims 2,4-9,21,23-27,62 and 63 have been cancelled.

Claims 17-20,22,28-33,40,42-46,48-52,54,55,57,58,60,61 are withdrawn.

Claims 3,10-16,34-39,41,47,53,56 and 59 have been amended herein.

Claims 1,3,10-13,15,16,34-39,41,47,53,56 are currently amended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3,10-13,15,16,34-39,41,47,53,56,59,62,63 remain rejected and newly added claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peery '396 in view of Jiang '108.

Peery discloses a rate controlling membrane comprising polyurethane or polyether blocked amides copolymers subsequently incorporated into a delivery device containing the drug leuprolide (see Abstract, Figs. 1 and 2 and col.5, line 66 to col.6, line 61). Peery et al. does not disclose that the rate controlling membrane is subjected to an elevated temperature below the melting temperature for a predetermined time and annealed.

Jiang discloses polyamide polymers similar to those taught by Peery used in the making of surgical devices such as drug delivery devices that are subjected to an elevated temperature below the melting temperature for a predetermined time which is annealing, and subsequently incorporated into a delivery device (see col.3, line 31 to col.4, line 7 and col.5, lines 14-50). Jiang disclose that the monofilament which is a suture can be annealed (see col.4, lines 6-7) causing the membrane to shrink thereby returning the membrane to its most relaxed state which is equivalent to Applicant's use of the specific temperatures and time periods used (see Instant application, Field of the Invention). Therefore, it would have been obvious to one of ordinary skill in the art to use any temperature and predetermined time including that of the instant claimed invention to anneal the membrane to return it to its most relaxed state in the absence of a factual showing of criticality of the times and temperatures claimed or a showing of unexpected results.

Response to Arguments

Applicant's arguments filed 11/17/03 have been fully considered but they are not persuasive. Applicant argues that hindsight reconstruction has been used to argue obviousness and there is no suggestion to combine the references. Applicant argues that Jiang does not teach or suggest use of a rate controlling membrane for subsequent incorporation into a delivery device. Jiang does not teach or suggest use of polyamide polymers that are annealed and subsequently incorporated into a delivery device. Jiang does not teach or suggest, alone or in combination with Peery et al., a rate controlling membrane that has been heated to particular temperatures for specific periods of time to (as described in the specification) effects a change in the morphology of the polymer that is stable at room temperature and which provides consistent membrane functionality over time. Jiang also does not teach or suggest that annealing the monofilament suture causes "the membrane to shrink thereby returning the membrane to its most relaxed state.

In response to applicant's argument that there is no suggestion to combine the references. It is the position of the examiner that Jiang '108 teaches polyamide polymers which are also similar to those taught by Peery '396 which are known for providing the same purpose in making surgical devices. The drug delivery devices are subjected to an elevated temperature below the melting temperature for a predetermined time, and subsequently incorporated into a delivery device (see col.3, line 31 to col.4, line 7 and col.5, lines 14-50). Hence, the '108 reference does teach that the monofilament which is a suture can be annealed (see col.4, lines 6 and 7), and it

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would have been obvious to one ordinary skill in the art at the time the invention was made to use any temperature and predetermined time including that of the instant claimed invention to anneal the membrane to return it to its most relaxed state in the absence of a factual showing of criticality of the times and temperatures claimed or a showing of unexpected results. Therefore the rejection set forth above is maintained for reasons of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

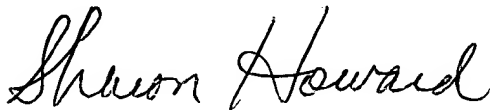
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard
July 19, 2004



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER